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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR		ATTORNEY DOCKET NO.
09/006,627	01/13/98	WALLIS	N	GM10127

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EXAMINER	
MONSHIPOURI, M	
ART UNIT	**PAPER NUMBER**
1652	5

DATE MAILED: 04/21/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/006,627	Applicant(s) Wallis et al.
	Examiner Maryam Monshipouri	Group Art Unit 1652

☐ Responsive to communication(s) filed on _____.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-12, 23, and 24* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1-12, 23, and 24* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 4

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-12 and 23-24, drawn to isolated nucleic acids encoding a Histidine Kinase from Staphylococcus aureus, vectors and hosts comprising the nucleic acids and a method of expressing the kinase polypeptide, classified in class 435, subclass 194.

II. Claims 13-14, drawn to Histidine Kinase polypeptides, classified in class 435, subclass 194.

III. Claim 15, drawn to antibodies against the polypeptide , classified in class 530, subclass 387.1.

IV. Claim 16, drawn to an antagonist, classification not determined. This is because the applicant refers to organic molecules, peptides, polypeptides and antibodies (see page 24) as antagonists. Since the classification depends on the chemical structure of the antagonist unless the type of antagonist is identified classification cannot be determined

V. Claim 17, drawn to methods of treatment of an individual using Histidine kinase polypeptides, classified in class 424, subclass 94.5.

VI. Claim 18, drawn to methods of treatment of an individual using antagonists to the polypeptide, classification not determined for the reasons given above for invention IV.

VII. Claim 19, drawn to a process for diagnosing a disease related to the expression or activity of the polypeptides, classified in class 435, subclass 6.

VIII. Claim 20, drawn to a method for identifying compounds which inhibit or activate the polypeptides, classified in class 435, subclass 15.

IX. Claims 21, drawn to a method of inducing an immunological response in a mammal comprising inoculating the mammal with Histidine Kinase polypeptides, classified in class 424, subclass 190.1.

X. Claim 22, drawn to a method of inducing an immunological response in a mammal comprising delivering vectors comprising nucleic acids to direct expression of Histidine Kinase, classified in class 514, subclass 44.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the polypeptides of invention II may be prepared synthetically which is entirely different method than that of invention I.

Inventions I, III and IV are patentably distinct each from the other because each product has a different chemical structure and function. Therefore these inventions have acquired a separate status in the art and require different search strategies each compared to the other.

Inventions I, V, VI, VIII, and IX are patentably distinct each from the other. This is because non of the methods utilizes the nucleic acids encoding the polypeptide at any step to reach its final goal. Further, the nucleic acids may be used in an entirely different method such as mutant preparation which is an entirely different method than each and every method recited for inventions: V, VI, VIII and IX. Therefore these inventions have acquired a separate status in the art and require different search strategies each from the other.

Inventions I, VII and X are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the nucleic acids of invention I may be used for mutant preparation which is an entirely different method than those of inventions VII and X.

Inventions II, III and IV are patentably distinct because each product has a different chemical structure and function. These inventions have acquired separate status in the art as evidenced by their separate classification.

Inventions II, V, VIII and IX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptides of invention II may be used for antibody

preparation which is an entirely different process than each and every method of inventions V, VIII and IX.

Inventions II, VI, VII, and X are patentably distinct each from the other because method inventions VI, VII and X do not utilize the polypeptides of invention II at any step to reach their final endpoints. Further, the polypeptides of invention II may be used for inhibitor/activator screening assay which is an entirely different method than each and every method inventions of Groups VI, VII and X, respectively.

Inventions III and IV are patentably distinct because each product has a different chemical structure and function. These inventions have acquired a separate status in the art as evidenced by their separate classification.

Inventions III, V, VI, VII and VIII are patentably district each from the other because non of the method inventions utilizes the antibody at any step to reach its final end point. Further, the antibody may be used for polypeptides detection which is an entirely different method than each and every invention: V, VI, VII and VIII, respectively.

Inventions III, IX and X are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the the antibody of invention III may be used for polypeptides detection which is an entirely different method than either invention IX or invention X.

Inventions IV, V, VII, VIII, IX and X are patentably distinct each from the other because non of the invention methods: V, VII, IX and X utilizes the antagonists. Further the antagonists may be used for signal transduction studies which is an entirely different method than any of the method inventions Groups V, VII, IX and X.

Inventions IV and VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antagonist of invention IV may be used for signal transduction studies which is an entirely different method than that of invention VII.

Inventions V, VI, VII, VIII, IX and X are patentably distinct each from the other because each method relates to Histidine polypeptides differently. Further, each method has different steps and different endpoints. These inventions have acquired a separate status in the art each from the other and require entirely different search strategies.

During a telephone conversation with Mr. T. Deibert on 3/29/99 a provisional election was made with traverse to prosecute the invention of group I, claims 1-12, 23 and 24. Affirmation of this election must be made by applicant in replying to this Office action. Claims 13-22 withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

DETAILED ACTION

Claims 1-12, 23 and 24 are under examination on the merits.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-12 and 23-24 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term " % identity" in claims 1-3, 23-24 is vague and indefinite. This term has been defined in the specification (page 31, second paragraph). However, the definition provided in the specification is non-specific, because it does not provide a specific software and the associated parameters chosen for its execution. The specification merely provides examples of the types of softwares that may be used and the way in which the analysis may be done. Therefore, based on the definition provided in the specification one of ordinary skill in the art cannot determine which specific software and associated analysis parameters to choose

in order to arrive at sequence identities claimed. Hence, claims 1 (and its dependent claims 5-12), as well as claims 2-3, 23 and 24 are vague and indefinite.

3. ***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 12, 21 and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Buchanan et al. (J. Bacteriol., 174, 1717-1725, 1992). The word "fragment" in the specification is defined as (see page 11, lines 17-21) as a variant polypeptide having an amino acid sequence that entirely is the same as part but not all of the polypeptides (i.e. SEQ ID NO:s 1-2). Buchanan et al. teach a polypeptide that entirely is the same as part but not all of SEQ ID NO:1 (see their nucleic acids 21789-21796 for perfect match to nucleic acids 156-164 of SEQ ID NO:1 of this invention). Therefore, Buchanan et al. anticipate claims 12, 21 and 22 for reciting the word "fragment".

6. No claims are allowed.

7. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Maryam Monshipouri, Ph.D. whose telephone number is (703) 308- 1083.

The Examiner can normally be reached daily from 8:30 A.M. to 4:30 P.M.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. P. Achutamurthy, can be reached at (703) 308-3804. The OFFICIAL fax number for Technology Center 1600 is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Maryam Monshipouri, Ph.D.

Patent Examiner

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PRIMARY EXAMINER
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